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U. S. Department of Agriculture

CHART ANALYSIS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT*

(Act approved June 25, 1938, 75th Cong., 3d Sess., 52 Stat., 1040, 21 U. S. C., sec. 301 et. seq.; amended June 23, 1939, 76th Cong., 1st Sess., 53 Stat. 853)

I. FOOD

DEFINITIONS	WHAT CONSTITUTES ADULTERATION	WHAT CONSTITUTES MISBRANDING	PROHIBITED ACTS
1	2	3	4
"Food" means: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. (201 (f)) [*General terms not peculiar to food, drugs, devices, or cosmetics*]: *"Label"* means: Display of written, printed, or graphic matter upon immediate container; and any requirement by act or regulation thereunder that something appear on label means it should also appear on any outside container or wrapper of retail package, or be easily legible through outside container or wrapper. (201 (k)) *"Labeling"* means: All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. (201 (m)) *"Immediate container"* does not include package liners. (201 (l)) *"Interstate commerce"* means: (1) Commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body. (201 (b)) *"Territory"* means: Any Territory or possession of U. S., including District of Columbia and excluding Canal Zone. (201 (a)) *"Department"* means: U. S. Department of Agriculture. (201 (c)) *"Secretary"* means: Secretary of Agriculture. (201 (d)) *"Person"* includes: Individual, partnership, corporation, and association. (201 (e))	*Food is adulterated if:* A. (1) It consists wholly or partly of any *filthy, putrid, or decomposed* substance, or is otherwise *unfit* for food; (402 (a) (3)) or (2) has been prepared, packed, or held under *insanitary conditions* whereby it may have become contaminated with filth or may have been rendered injurious to health; (402 (a) (4)) or (3) its *container* is composed wholly or partly of any poisonous or deleterious substance which may render contents injurious to health; (402 (a) (6)) or (4) it bears or contains any *poisonous or deleterious substance* which may render it injurious to health (*but* not adulterated under this clause if: (*a*) Secretary has established a tolerance, limiting amount of such added substance; or (*b*) it is not an added substance, and quantity thereof does not ordinarily render it injurious to health); (402) (a) (1), (406 (a)) or (5) bears or contains any *added poisonous or added deleterious substance* which is "*unsafe*," i. e.: (*a*) Is not required in the production of the food, and (*b*) can be avoided by good manufacturing practice (*but* when such substance is so required or cannot be so avoided, Secretary's regulations shall limit quantity to extent necessary for protection of public health; and any quantity exceeding limits so fixed shall also be deemed "unsafe"); (402 (a) (2), 406 (a)) or (6) is wholly or partly the product of a *diseased animal* or of one that died not by slaughter. (402 (a) (5)) B. (1) Any valuable constituent has been wholly or partly *omitted or abstracted* from the food; (402 (b) (1)) or (2) any substance has been *substituted* wholly or partly for the food; (402 (b) (2)) or (3) damage or inferiority has been *concealed* in any manner; (402 (b) (3)) or (4) any substance has been added or mixed or packed with it, so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is. (402 (b) (4)) C. It bears or contains a *coal-tar color* other than one from batch certified in accordance with Secretary's regulations. (*But:* This does not apply to citrus fruit bearing or containing coal-tar color commonly used prior to act for coloring citrus fruit, and application for listing of color has been made under act, and not been acted on by Secretary.) (402(c)) D. It is *confectionery*, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 percent, natural gum, and pectin. (*But:* This does not apply to any confectionery by reason of its containing less than one-half of 1 percent by volume of alcohol derived solely from use of flavoring extracts, or to any chewing gum by reason of its containing harmless, nonnutritive masticatory substances.) (402 (d))	*Food is misbranded if:* (1) Its labeling is *false or misleading* in any particular. (403 (a)) (And in determining whether misleading shall take into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also extent to which labeling fails to reveal facts material in light of such representations, or material with respect to consequences which may result from use of article to which labeling relates, under conditions of use prescribed in labeling thereof or under such conditions of use as are customary or usual.) (201 (n)) (2) Is in package form, and label does not contain: (*a*) *Name and place of business* of manufacturer, packer, or distributor; and (*b*) accurate statement of *quantity of contents* in terms of weight, measure, or numerical count. (*But:* Under (*b*) above, reasonable variations shall be permitted, and exemptions as to small packages shall be established by Secretary's regulations.) (403 (e)) (3) Any word, statement, or other information required by act or regulation thereunder to be on label or labeling is *not prominently placed thereon* with such conspicuousness (as compared with other things in labeling) and in such terms as to render it likely to be *read and understood* by ordinary individual under customary conditions of purchase and use. (403 (f)) (4) Its *container* is so made, formed, or filled as to be misleading. (403 (d)) (5) It is offered for sale under *name of another* food. (403 (b)) (6) It is an *imitation* of another food (*unless* label bears, in type of uniform size and prominence, word "imitation" and immediately thereafter, name of food imitated). (403 (c)) (7) It purports to be or is represented as a food for which a *definition and a standard of identity* has been prescribed by regulations as provided by section 401 and (*a*) does not conform to such definition and standard, or (*b*) label does not bear name of food specified in definition and standard and, ~~insofar as may be required by such regulations~~, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food. (403 (g)) (Provisions in paragraph immediately above relating to artificial coloring shall not apply in case of butter, cheese, or ice cream.) (403 (k)) (8) It purports to be or is represented as a food for which a *standard of quality* has been prescribed by regulations, and quality falls below such standard, and label does not bear, in manner and form specified by regulations, a statement that it falls below such standard. (403 (h) (1)) It purports to be or is represented as food for which standard or standards of *fill of container* have been prescribed by regulations, and falls below applicable standard, and label does not bear, in manner specified by regulations, statement that it falls below such standard. (403 (h) (2)) (9) It is *not* a food for which definition and standard of identity has been established, and label does *not* bear (*a*) common or usual name of the food, if any there be, and (*b*) common or usual name of each ingredient, if fabricated from two or more ingredients; *except that* spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each (*but* to extent that compliance with (*b*) above is impracticable or results in deception or unfair competition, exemptions shall be established by Secretary). (403 (i)) (Provisions in paragraph immediately above relating to artificial coloring shall not apply in case of butter, cheese, or ice cream.) (403 (k)) (10) It purports to be or is represented for *special dietary uses*, and label does not bear such information concerning its vitamin, mineral, and other dietary properties as Secretary determines by regulations to be necessary, for fully informing purchasers as to value for such uses. (403 (j)) (11) It bears or contains any *artificial flavoring, artificial coloring,* or *chemical preservative* and does not bear labeling stating that fact (*but* to extent that compliance is impracticable, exemptions shall be established by Secretary). (403 (k)) (Provisions of this paragraph with respect to artificial coloring shall not apply to butter, cheese, or ice cream.) (403 (k))	*Following acts and causing thereof are prohibited:* (1) *Introduction or delivery for introduction* into interstate commerce of any food that is adulterated or misbranded. (301 (a)) (2) Adulteration or misbranding of any food *in interstate commerce*. (301 (b)) (3) *Receipt* in interstate commerce of any food that is adulterated or misbranded, and *delivery* or proffered delivery thereof for pay or otherwise. (301 (c)) (4) Introduction or delivery for introduction into interstate commerce of any article in violation of *emergency permit regulations*. (See column 12.) (301 (d)) (5) *Refusal* to permit access to or copying of *records* showing interstate movements of food or the holding thereof after such movement, and the quantity, shipper, and consignee thereof. (301 (e)) (See column 26.) (6) *Refusal* to permit *entry* at reasonable times of any factory, warehouse, or establishment in which food is manufactured, processed, packed, or held for introduction into interstate commerce or is held after such introduction, or refusal to permit entry of any vehicle being used to transport or hold such food in interstate commerce; or refusal to permit *inspection* at reasonable times of such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished *materials, containers, and labeling therein*. (301 (f)) (See column 26.) (7) *Manufacture* within any *Territory* of adulterated or misbranded food. (301 (g)) (8) Giving of a *false guaranty* or undertaking that 301 (a) or 301 (d) above has not been violated (*except* when the giver relied upon guaranty or undertaking to same effect, with signature and address of United States resident from whom he received in good faith the food), or the giving of a false guaranty signed by manufacturer of coal-tar color that there is no adulteration through use of uncertified coal-tar color. (301 (h)) (9) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by *emergency permit regulations* or regulations as to *coal-tar colors*. (301 (i)) (See columns 7 and 12.) (10) Using by any person to his own advantage or revealing other than to Secretary or Department officers or employees, or to court when relevant in judicial proceeding under act, any *information* acquired under authority of provisions as to *emergency permit control* or *factory inspection*, concerning any method or process which as a *trade secret* is entitled to protection. (301 (j)) (See columns 12 and 26.) (11) Alteration, mutilation, destruction, obliteration, or removal of all or any part of labeling of, or doing of any other act with respect to, a food—if act is done while article is held for sale after shipment in interstate commerce and *results in such article being misbranded*. (301 (k))

ESTABLISHMENT OF STANDARDS AND OTHER ADMINISTRATIVE REGULATIONS						
STANDARDS		OTHER ADMINISTRATIVE REGULATIONS				GENERAL AUTHORITY AND PROCEDURE
Definitions and standards of identity	Standards of quality and of fill of container	1. Coal-tar colors. 2. Requests for parts of official samples. 3. Emergency permit regulations.	1. Limited quantity of added poisonous or added deleterious substances in food. 2. Dietary properties of food. 3. Taste and assay of drugs. 4. Drugs liable to deterioration. 5. Designating habit-forming drugs.	*Exemptions:* 1. From labeling requirements in case of certain containers of fresh fruits and vegetables. 2. From labeling requirements in case of certain articles to be labeled, processed, or repacked elsewhere. 3. From specifying artificial coloring, flavoring, and chemical preservative. 4. From specifying ingredients. 5. From stating quantity of contents. 6. From requirement as to furnishing parts of official samples. 7. From provisions as to new drugs. 8. From requirement that drugs and devices bear adequate directions for use.	Imports and exports	1. General authority. 2. Holding of hearings. 3. Orders based on hearings.
5	6	7	8	9	10	11
1. Whenever Secretary thinks it will promote honesty and fair dealing in interest of consumers, he shall make regulations fixing for any food under its common or usual name so far as practicable, a reasonable *definition and standard of identity*, a reasonable standard of quality, and/or reasonable standards of fill of container. *But:* No definition and standard of identity shall be established for *fresh or dried fruits, fresh or dried vegetables, or butter* (with exception that they *may* be established for *avocados, cantaloups, citrus fruits, and melons* and in such case shall relate *only to maturity* and *to effects of freezing*). In prescribing definition and standard of identity for any food or class of food in which optional ingredients are permitted, Secretary shall, to promote honesty and fair dealing in interest of consumers, designate the optional ingredients which shall be named on label. (401) 2. Definitions and standards of identity shall be effective for enforcement of this act notwithstanding definitions and standards contained in other laws of United States and regulations promulgated thereunder. (701 (d))	1. Whenever Secretary thinks it will promote honesty and fair dealing in interest of consumers, he shall make regulations fixing for any food under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable *standard of quality, and/or reasonable standards of fill of container*. (*But:* No standard of *quality* shall be established for *fresh or dried fruits, fresh or dried vegetables, or butter.*) In prescribing any standard of *quality* for any *canned* fruit or any *canned* vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruits or vegetables. 2. In prescribing any standard of *fill of container*, Secretary shall give due consideration to natural shrinkage in storage and transit of fresh natural food and to need for necessary packing and protective material. (401)	1. *Coal-tar colors:* Secretary shall make regulations providing for *listing* of coal-tar colors which are harmless and suitable for use in food; and for *certification* of batches of such colors with or without harmless diluents. (406 (b)) Regulations shall specify such fees to be paid for listing and certification as are necessary to provide, maintain, and equip an adequate service for such purposes. (706) 2. *Samples:* Secretary authorized, by regulations, to make reasonable exceptions from and *impose reasonable terms and conditions relating* to provision that: Where sample of article is collected for analysis, Secretary shall, upon request provide part thereof for examination or analysis by any person named on label of article, or owner thereof or his attorney or agent. (702 (b)) (See column 25.) 3. *Emergency permit regulations:* If Secretary finds that interstate commerce in any class of food may be injurious to health because of contamination with micro-organisms in the manufacture, processing, or packing thereof in any locality, and injurious nature can not be determined after entry into interstate commerce, he shall make *regulations providing for issuance of* certain permits. (404 (a)) (See column 12.)	1. *Added poisonous or added deleterious substances:* Where an added poisonous or added deleterious substance is required in production of a food, or cannot be avoided by good manufacturing practice, Secretary shall make regulations limiting the quantity therein or thereon to extent he finds necessary for protecting public health (and any quantity exceeding limits fixed shall make food adulterated). In determining quantity to be tolerated, Secretary shall consider extent to which use of substance is required or cannot be avoided in production of article, and other ways in which consumer may be affected by same or other poisonous or deleterious substances. (406 (a)) 2. *Dietary properties:* Secretary's regulations as to information on label regarding dietary properties (if food purports to be or is represented for special dietary uses) must be complied with, or food will be misbranded. (403 (j)) (See No. 10 in column 3.)	1. *For certain containers of fruits and vegetables:* Secretary shall make regulations exempting small open containers of fresh fruits and fresh vegetables from any labeling requirement of act. (405) 2. *For articles to be processed, repacked, etc.:* Secretary shall make regulations exempting from any labeling requirements of act, food which is, in accordance with practice of trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed—but exemption is on condition that such food is not adulterated or misbranded upon removal from such processing, labeling, or repacking establishment. (405) 3. *From specifying artificial coloring, artificial flavoring, preservative:* Secretary shall make exemptions from requirement (to extent that compliance is impracticable) that any artificial flavoring, artificial coloring, or chemical preservative should be stated on label to avoid misbranding. (403 (k)) (See No. 11 in column 3.) 4. *From specifying ingredients:* Secretary shall make exemptions from requirement (to extent that compliance is impracticable or results in deception or unfair competition) that for certain foods, label state names of ingredients to avoid misbranding. (403 (i)) (See No. 9 in column 3.) 5. *From stating quantity of contents:* Secretary shall make regulations exempting small packages from, and permitting variations from, requirement that packaged food should, in order not to be misbranded, have accurate statement of quantity of contents in terms of weight, measure, or numerical count. (403 (e)) 6. *From furnishing parts of samples:* Secretary authorized, by regulations, to make *reasonable exceptions* from and impose reasonable terms and conditions relating to provision that: Where sample of article is collected for analysis, Secretary shall upon request provide part thereof for examination or analysis by any person named on label of article, or owner thereof, or his attorney or agent. (702 (b)) (See column 25.)	1. Secretary shall jointly with Secretary of Treasury, make regulations for efficient enforcement of section 801 regarding imports and exports, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time after due notice, as Secretary of Agriculture shall determine. (701 (b)) (See column 18.) 2. Where consignee of imported article which has been refused admission, wishes to avoid destruction of article by exporting it, such export to be under regulations prescribed by Secretary of Treasury. (801 (b)) (See column 18.)	1. *General authority:* Authority to make regulations for efficient enforcement of act is vested in Secretary of Agriculture (except as powers are granted to Secretary of Treasury in matter of exports and imports). (701 (a)) (See column 18.) 2. *Holding of hearings:* (*a*) Hearings authorized or required by act shall be conducted by Secretary or such officer or employee as he may designate. (701 (c)) (*b*) Secretary, on own initiative, or on application of any interested industry or substantial portion thereof stating reasonable grounds therefor, *shall* hold public hearing upon proposal to issue, amend, or repeal any regulation contemplated by sections of act dealing with: (1) *A definition and standard of identity, a standard of quality and standards of fill of container.* (2) Information required on label as to *dietary properties* of food. (3) *Emergency permit control* of food. (4) Limitation of quantity of added *poisonous* or added *deleterious* substances to food. (5) Listing and certifying of *coal-tar colors*. (701 (e)) (*c*) Secretary shall give appropriate notice of hearing, and notice shall state proposal in general terms and specify time and place for public hearing to be held thereon not less than 30 days after date of notice; except that hearings involving emergency permit control may be held within reasonable time to be fixed by Secretary, after notice thereof. (701 (e)) (*d*) At hearing, any interested person may be heard in person or by his representative. (701 (e)) (*e*) Certified copy of transcript of record and proceedings shall be furnished by Secretary to any interested party at his request, and payment of costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this act, irrespective of whether proceedings with respect to order have previously been instituted or become final under provisions of 701 (f). (701 (g)) (Regarding judicial review, see columns 28, 29.) 3. *Orders based on hearings:* As soon as practicable after completion of hearing, Secretary shall by order make public his action in issuing, amending, or repealing regulations or determining not to take such action. Order shall be based on substantial evidence of record at hearing and shall set forth detailed findings of fact on which order is based. No such order shall take effect prior to ninetieth day after issued; *except* that if Secretary finds emergency conditions exist, necessitating earlier effective date, order shall specify findings as to such conditions and shall take effect at such earlier date as Secretary shall specify therein to meet emergency. (701 (e)) (For judicial review of orders, see columns 28, 29.)

EMERGENCY CONTROL	NEW DRUGS		TOLERANCES	EXEMPTIONS		IMPORTS AND EXPORTS
	1. General authority and conditions as to applications. 2. Service of orders.	1. Suspension of granted application. 2. Revocation of refusal of application. 3. Appeal from suspension or refusal. 4. Exemptions.		To persons	To products	
12	13	14	15	16	17	18
1. Whenever Secretary finds after investigation that distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect public health; and after effective date of such regulations and during such temporary period, there shall not be introduced or delivered for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer, unless he holds such permit. (404 (a)) 2. Secretary is authorized to suspend any such permit immediately upon notice, if it is found that any of conditions of permit have been violated. Holder of suspended permit is privileged at all times to apply for reinstatement and Secretary shall, immediately after prompt hearing and inspection of establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain conditions of permit, as originally issued or as amended. (404 (b)) 3. Any officer or employee designated by Secretary shall have access to any factory or establishment, operator of which holds permit, for seeing whether conditions of permit are being complied with, and denial of access shall be ground for suspension of permit until such access is freely given by operator. (404 (c))			1. Secretary's regulations shall *permit reasonable variations* from requirement that information on label of packaged food should include accurate *statement of quantity of contents* in terms of weight, measure, or numerical count. (403 (e)) 2. Requirement that *confectionery* should not contain *alcohol*, not applicable to confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from flavoring extracts. (402 (d)) 3. Where *added poisonous or added deleterious substance* is required in production of food or cannot be avoided by good manufacturing practice, regulations by Secretary shall *limit quantity* therein or thereon to extent he finds necessary for protecting public health. (406 (a)) (See column 8.)	1. No person is subject to fine and imprisonment penalties (see column 20) *for:* (*a*) Having received article in interstate commerce and in good faith delivered it or proffered delivery (*unless* refuses to furnish name and address of person from whom he purchased or received article and copies of any documents pertaining to the delivery to him. (303 (c) (1)) *Or for:* (*b*) Having introduced or delivered for introduction into interstate commerce any food in violation of prohibitions as to adulteration or misbranding, or in violation of emergency permit regulations, *if* he establishes *guaranty* or undertaking containing signature and address of United States resident from whom he received articles in good faith, that no such violation has occurred. (303 (c) (2)) *Or for:* (*c*) Having introduced or delivered for introduction into interstate commerce any food adulterated by coal-tar color which was not from a certified batch, *if* he establishes *guaranty* or undertaking containing signature and address of manufacturer of the color, to effect that such color was from certified batch. (303 (c) (3)) 2. *Evidence* obtained by inspecting records under section 703 (see column 26) *shall not be used in criminal prosecution of person from whom obtained.* (703) 3. *Carriers*, although subject to provisions regarding access to records, shall not be subject to other provisions of act by reason of their receipt, carriage, holding, or delivery of food, in usual course of business as carriers. (703)	1. Secretary shall establish exemptions as to *small packages* from requirement that packaged food in order not to be misbranded should have label with accurate statement of quantity of contents. (403 (e) (2)) 2. Secretary's regulations shall exempt from labeling requirements, (*a*) *small open containers of fresh fruits and fresh vegetables* and (*b*) food which is, by practice of the trade, *to be processed, labeled, or repacked* in substantial quantities at establishments other than those where originally processed or packed—but exemption is on condition food is not adulterated or misbranded on removal from such other establishment. (405) 3. Provision that food adulterated if has *coal-tar color* other than from certified batch is not applicable to *citrus fruit*, if application for listing of color has not been acted on by Secretary and such color was commonly used to color citrus fruit prior to act. (402 (c)) 4. Provision that (with certain exceptions) confectionery adulterated if contains nonnutritive article or substance is not applicable to *chewing gum* by reason of its containing harmless, nonnutritive masticatory substances. (402 (d)) (See column 2 (D).) 5. Secretary shall establish exemptions (to extent that compliance is impracticable or results in deception or unfair competition) from requirement that: For food for which no definition and standard of identity has been established, label shall state *common or usual name of each ingredient*, with exception that *spices, flavorings, and colorings*, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each. (403 (i)) And provisions of above paragraph with respect to artificial coloring shall not apply in case of *butter, cheese, or ice cream*. (403 (k)) 6. Provisions of 403 (g) with respect to artificial coloring (see No. 7 under column 3) shall not apply in case of *butter, cheese, or ice cream*. (403 (k)) 7. Secretary shall establish exemptions (to extent compliance is impracticable) from requirement that any *artificial flavoring, artificial coloring, or chemical preservative* be stated on label to avoid misbranding. Requirement as to artificial coloring shall not apply to *butter, cheese, or ice cream*. (403 (k)) 8. Secretary shall not, with certain exceptions (see columns 5 and 6) establish any definitions, standards of identity, or standards of quality for *fresh or dried fruits, fresh or dried vegetables, or butter*. (401) 9. Article *intended for export* and not sold or offered for sale in domestic commerce is not subject to the adulteration and misbranding provisions if it accords to specifications of foreign purchaser, is not in conflict with laws of country to which intended for export, and is labeled on outside of shipping package to show it is intended for export. (801 (d)) 10. See also No. 2 in column 31.	1. *Imports:* (*a*) Secretary of Treasury shall deliver to Secretary of Agriculture, on his request, samples of food being imported or offered for import into United States, giving notice thereof to owner or consignee, who may appear before Secretary of Agriculture and have right to introduce testimony. If appears from examination of samples or otherwise that article has been manufactured, processed, or packed under insanitary conditions, or, (1) Is forbidden or restricted in sale in country where produced or from which exported, or: (2) Is adulterated or misbranded—then such article shall be refused admission. (801 (a)) (*b*) Secretary of Treasury shall refuse delivery to consignee and cause destruction of article refused admission unless it is exported by consignee within 3 months from date of notice of refusal, under such regulations as Secretary of Treasury may prescribe. However, pending examination and decision, Secretary of Treasury may deliver article to consignee on execution of bond as liquidated damages for full invoice value thereof and duty thereon, and upon consignee's refusal to return article or part thereof to Secretary of Treasury when demanded for any purpose, he shall forfeit bond as liquidated damages. (801 (b)) (*c*) Charges for storage, cartage, and labor on article refused admission or delivery shall be paid by owner or consignee and in default of such payment shall constitute lien against any future importations made by owner or consignee. (801 (c)) 2. *Exports:* Article intended for export shall not be deemed adulterated or misbranded if it: (*a*) Accords to specifications of foreign purchaser; (*b*) is not in conflict with laws of country to which it is intended for export; and (*c*) is labeled on outside of shipping package to show it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any provisions of this act. (801 (d))

ENFORCEMENT								
		SEIZURES				EXAMINATION, INVESTIGATION, INSPECTION		DIFFERENT TREATMENT FOR MINOR VIOLATIONS
Injunctions	Criminal proceedings 1. Procedure. 2. Fine and imprisonment.	General authority and procedure	1. Limitation on number of libels for misbranding. 2. Removal of certain such libels to another district.	Consolidation of libels involving same claimant and issues in different jurisdictions	Disposal of condemned articles	General investigation, examination, sampling	1. Access to records. 2. Factory inspection.	
19	20	21	22	23	24	25	26	27
1. District Courts of United States, and United States Courts of Territories shall have jurisdiction for cause shown, and subject to provisions of section 17 (relating to notice to opposite party) of Clayton Act, of October 15, 1914, as amended, to restrain the doing of any of the prohibited acts listed in section 301, except paragraphs (*e*), (*f*), (*h*), (*i*), and (*j*). (See column 4) (302 (a)) 2. Where violation of injunction or restraining order issued under this section also constitutes violation of act, trial shall be by court; or on demand of accused shall be by jury. Trial shall be conducted in accordance with practice and procedure applicable to proceedings under section 22 of Clayton Act of October 15, 1914, as amended. (302 (b)) 3. Proceeding to restrain violations of act shall be by and in name of United States. Notwithstanding provisions of section 876 of Revised Statutes, subpenas for witnesses who are required to attend a court of United States, in any district, may run into any other district in any such proceeding. (307)	1. *Procedure:* (*a*) Before any violation of act is reported by Secretary to any United States attorney for institution of a criminal proceeding, person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views either orally or in writing, with regard to such contemplated proceeding. (305) (*b*) Proceedings for enforcement of act shall be by and in name of United States. Notwithstanding provisions of section 876 of Revised Statutes, subpenas for witnesses who are required to attend a court of United States, in any district, may run into any other district in any such proceedings. (307) 2. *Fine and imprisonment:* (*a*) Any person committing any of prohibited acts listed in section 301 (see column 4) shall be guilty of misdemeanor and on conviction be subject to imprisonment for not more than 1 year or fine of not more than $1,000, or both; and if violation is committed after conviction of such person under this section has become final, shall be subject to imprisonment for not more than 3 years, or fine of not more than $10,000, or both. (303 (a)) (*b*) Notwithstanding above provisions, if violation of section 301 is with intent to defraud or mislead, penalty shall be imprisonment for not more than 3 years or fine of not more than $10,000, or both. (303 (b)) (*c*) Certain persons not subject to penalties of 303 (a) above. (See column 16.)	1. Any food that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, because of emergency permit regulations, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on *libel* of information and condemned in any *district court of United States* within jurisdiction of which article is found, subject to certain limitations on number of libel proceedings. (See next column.) (304 (a)) 2. The article shall be liable to seizure by process pursuant to the libel, and procedure in cases under this section shall conform, as nearly as may be, to *procedure in admiralty*; except that on demand of either party to any issue of fact joined in any such case shall be tried by *jury*. (304 (b)) 3. At any time after seizure, up to a reasonable time before trial, court shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain *representative sample* of article seized (and as regards fresh fruits or fresh vegetables, a true copy of analysis on which proceeding is based and any identifying marks or numbers of packages from which samples analyzed were obtained). (304 (c)) 4. When decree of condemnation is entered against article, court costs and fees, and storage and other proper *expenses*, shall be *awarded against* person, if any, intervening as *claimant* of article. (304 (e))	1. *Limitation on number:* For any alleged misbranding, not more than one libel for condemnation shall be instituted and if there is already one such proceeding pending in a court, no additional libel proceedings based on same alleged misbranding shall be instituted. *But*, foregoing limitations shall not apply where: (1) Such misbranding has been basis of prior judgment in favor of United States in a criminal injunction or libel for condemnation proceeding under this act, or (2) Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of Department, that the misbranded article is dangerous to health or that its labeling is fraudulent, or would be in a material respect misleading to the injury or damage of purchaser or consumer. (304 (a)) 2. *Removal to another district:* In any case where number of libel proceedings for misbranding is limited to one as above provided, the proceeding pending or instituted shall, on application of claimant seasonably made, be removed for trial to any district agreed on by stipulation between parties, or (in case of failure to so stipulate within reasonable time) claimant may apply to court of district in which seizure has been made, and such court (after giving United States attorney for district reasonable notice and opportunity to be heard) shall by order, unless good cause to contrary is shown, specify a district of reasonable proximity to claimant's principal place of business, to which case shall be removed for trial. (304 (a)) Clerk of court from which removal is made shall promptly transmit to court in which case is to be tried, all records in the case necessary for such court's exercising jurisdiction. And such court shall have same powers and duties, for purposes of the case, that the court from which removal was made would have had if case had not been removed. (304 (f))	Where libel for condemnation proceedings involving same claimant and same issues of adulteration or misbranding are pending in two or more jurisdictions, they shall upon application of claimant seasonably made to court of one such jurisdiction, be consolidated for trial by order of such court and tried in (1) any district selected by claimant where one of such proceedings is pending, or (2) a district agreed on by stipulation between parties. If no order for consolidation is so made within reasonable time, claimant may apply to court of one such jurisdiction and such court (after giving United States attorney for district reasonable notice and opportunity to be heard) shall by order, unless good cause to contrary is shown, specify a district of reasonable proximity to claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. But order of consolidation shall not apply so as to require removal of any case whose date for trial has been fixed. Court granting order of consolidation shall promptly notify other courts having jurisdiction of cases covered thereby. (304 (b)) Clerk of court from which removal is made shall promptly transmit to court in which case is to be tried, all records in the case necessary for such court's exercising jurisdiction. And such court shall have same powers and duties, for purposes of the case, that the court from which removal was made would have had if case had not been removed. (304 (f))	Condemned food shall, after entry of decree, be disposed of *by destruction or sale* as court may in accordance with provisions of this section, direct, and proceeds thereof, if sold, less legal costs and charges, shall be paid into United States Treasury. But such article shall not be sold under such decree contrary to provisions of this act or laws of jurisdiction in which sold. *However*, after entry of decree and upon payment of costs of such proceedings and execution of good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to provisions of act or laws of any State or Territory in which sold, court may by order direct that such article *be delivered to owner to be destroyed or brought into compliance with* provisions of act, under supervision of officer or employee designated by Secretary; and expenses of such supervision shall be paid by person obtaining release of article under bond. (But where food is condemned because it may not under emergency permit regulations be introduced into interstate commerce, it shall be disposed of by destruction.) (304 (d))	1. Secretary authorized to conduct examinations and investigations for purposes of act, through officers and employees of Department of Agriculture or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof duly commissioned by Secretary as an officer of Department. In the case of food packed in a Territory, Secretary shall attempt to inspect it at first point of entry within any State or District of Columbia, when in his opinion, and with due regard to enforcement of all provisions of act, facilities at his disposal will permit such inspection. (702 (a)) 2. Where sample of food is collected for analysis, Secretary shall on request provide part of such official sample for examination or analysis by any person named on label of article, or owner thereof or his attorney or agent. (*But:* Secretary authorized by regulations to make such reasonable exceptions, terms, and conditions relative to this subsection as he finds necessary for proper administration of act.) (702 (b))	1. *Access to records:* (*a*) Records of any department or independent establishment in executive branch of the Government shall be open to inspection by any official of Department of Agriculture duly authorized by Secretary to make such inspection. (702 (c)) (*b*) Carriers engaged in interstate commerce, and persons receiving food in interstate commerce or holding such articles so received, shall on request of officer or employee designated by Secretary, permit such officer or employee at reasonable times to have access to and to copy *all records showing movement of any food in interstate commerce or holding thereof during or after such movement, and quantity, consignee, and shipper thereof.* Unlawful for such carrier or person to fail to permit access to and copying of records when request is accompanied by *written statement specifying nature or kind of food* to which such request relates. (703) (See also No. 2 and No. 3, in column 16.) 2. *Factory inspection:* Officers or employees designated by Secretary, after first making request and obtaining permission (see No 6 in column 4) of owner, or operator, or custodian thereof, are authorized: (1) To enter, at reasonable times, any *factory, warehouse, or establishment* in which food is manufactured, processed, packed, or held, for introduction into interstate commerce or is held after such introduction; or to enter any *vehicle* being used to transport or hold such food in interstate commerce; and (2) to inspect at reasonable times, such factory, warehouse, establishment, or vehicle and all *pertinent equipment, finished and unfinished materials, containers, and labeling* therein (704)	Nothing in this act shall be construed as requiring Secretary to report for prosecution or for institution of libel or injunction proceedings, minor violations of this act whenever he believes that public interest will be adequately served by a suitable *written notice of warning*. (306)

JUDICIAL REVIEW OF CERTAIN REGULATIONS		MISCELLANEOUS	RELATION TO OTHER LAWS
Remedies available for obtaining judicial review	Scope of review 1. General. 2. When court may order additional evidence taken before Secretary.	1. Publicity of decisions and to information aiding the consumer. 2. Limited control over advertising.	1. To old Food and Drug Law. 2. To other laws.
28	29	30	31
1. In case of actual controversy as to validity of any order regarding issuance, amendment, or repeal of certain regulations (i. e., those listed in columns 5, 6, 7, 8—omitting that as to requests for samples) *any person who will be adversely affected by order* may at any time prior to ninetieth day after issuance of order, file petition with *United States Circuit Court of Appeals* for circuit wherein person resides or has principal place of business, for judicial review of order. Summons and petition may be served at any place in United States; and promptly upon such service, Secretary shall certify and file in court, transcript of proceedings and record on which he based his order. (701 (f) (1)) 2. Judgment of court affirming or setting aside wholly or partly, Secretary's order, *shall be final, subject to review by Supreme Court of United States* on certiorari or certification as provided in sections 239 and 240 of Judicial Code, as amended. (701 (f) (4)) 3. Above remedies for judicial review shall be *in addition to* and not in substitution for *any other remedies provided by law*. (701 (f) (6)) 4. Action instituted for judicial review shall survive notwithstanding change in person occupying office of Secretary, or any vacancy in such office. (701 (f) (5))	1. *General:* (*a*) Findings of Secretary as to facts, if supported by substantial evidence shall be conclusive. (701 (f) (3)) (*b*) Court shall have jurisdiction to affirm or set aside order in whole or in part, temporarily or permanently. And if order is one which refuses to issue, amend, or repeal a regulation, and order is not in accordance with law, court shall by its judgment *order Secretary to take action* regarding such regulation, in accordance with law. (701 (f) (3)) 2. *When court may order additional evidence taken before Secretary:* If petitioner for review applies to court for leave to adduce additional evidence and satisfies court that such evidence is material, and that there were reasonable grounds for failure to adduce such evidence in proceeding before Secretary, court may order such additional evidence (and evidence in rebuttal thereof) to be taken before Secretary and to be adduced upon the hearing in such way as to the court may seem proper. Secretary may modify his findings as to facts or make new findings, by reason of the additional evidence, and shall file such modified or new findings and his recommendation, if any, for modification or setting aside of his original order, with return of such additional evidence. (701 (f) (2))	1. *Publicity:* (*a*) Secretary shall cause to be published from time to time, reports summarizing all judgments, decrees, and court orders rendered under the act including nature of charge and disposition thereof. (705 (a)) (*b*) Secretary may also cause to be disseminated information regarding food in situations involving, in Secretary's opinion, imminent danger to health or gross deception of consumer. Nothing in this section shall be construed to prohibit Secretary from collecting, reporting, and illustrating results of Department's investigations. (705 (b)) 2. *Limited control over advertising:* Act covers such advertising as appears on label of article and matter accompanying the article. (See definitions of "label" and "labeling" in column 1.) (201 (k)) (201 (m))	1. *To old Food and Drug Law:* Food and Drug Law of 1906, as amended, remains in force until effective date of new act, i. e., until June 25, 1939, with following exceptions: (*a*) There shall be effective immediately after June 25, 1938, Secretary's authority to *make regulations* and *hold hearings* under section 701, and authority to designate food having common or usual names and to exempt such food from requirement that label state common or usual names of ingredients, in order to permit making and application of definitions and standards of identity therefor. (902 (a)) (*b*) There shall be effective immediately after May 2, 1939, section 706 as to listing and certification of coal-tar colors (see No. 1 in column 7). (Act of May 2, 1939, c. 107, title I, 53 Stat. 631.) (*c*) Effective date of labeling provisions in sections 402 (c); 403 (e) (1); 403 (g), (h), (i), (j), (k) (see column 3) is *postponed until January 1, 1940*. (Act of June 23, 1939, c. 242, sec. 1 (a), 53 Stat. 853.) (*d*) Secretary shall make regulations further *postponing to July 1, 1940*, effective date of provisions in (c) above (excluding section 402 (c)) with respect to lithographed labeling manufactured prior to February 1, 1939, and to containers bearing labeling which prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused, or blown on or in such containers, where compliance with said foregoing provisions would be unduly burdensome by causing loss of valuable stocks of such labeling or containers and where such postponement would not prevent public interest from being adequately served. However, postponement shall not apply to labeling which would not have complied with Food and Drug Act of 1906, as amended. (Act of June 23, 1939, c. 242, sec. 1 (b), 53 Stat. 853.) (*e*) Provisions of Food and Drug Act of 1906, as amended, authorizing Secretary to establish standard of quality, condition and/or fill of container for *canned food*, and requiring that if canned food falls below standard, that fact must be indicated on label; and all regulations promulgated under those provisions, and any parts of 1906 act, as amended, relating to enforcement of those provisions and regulations, are to *remain in force until January 1, 1940*. (Act of June 23, 1939, c. 242, sec. 2 (a), 53 Stat. 853.) (*f*) Provisions of Food and Drug Act of 1906, as amended, to extent that they impose or authorize imposition of any requirement imposed by section 403 (k) of 1938 act regarding *artificial flavoring, artificial coloring, and chemical preservative* (see No. 11 in column 3), are to *remain in force until January 1, 1940*. (Act of June 23, 1939, c. 242, sec. 2 (b), 53 Stat. 853.) (*g*) Provisions of Food and Drug Act of 1906, as amended, providing for inspection and certification service upon application of packers of *sea food* shall remain in force and effect and be applicable to provisions of this act. (902 (a)) 2. *To other laws:* (*a*) Following laws shall remain in force and effect and be applicable to provisions of this act: (1) Act of March 4, 1923, defining *butter* and providing a standard therefor. (2) Act of July 24, 1919, defining *wrapped meats* as in package form. (*b*) *Meat and meat-food products* are exempt from provisions of act, to extent of application or extension thereto of Meat Inspection Act of March 4, 1907, as amended. (902 (b)) (*c*) Nothing in act in any way affects, modifies, repeals, or supersedes provisions of *Virus, Serum, and Toxin Act* of July 1, 1902; *Filled Cheese Act* of June 6, 1896; *Filled Milk Act* of March 4, 1923; or *Import Milk Act* of February 15, 1927. (902 (c)) (*d*) Definitions and standards of identity shall be effective for enforcement of act, notwithstanding definitions and standards in other laws of United States and regulations thereunder. (701 (d))

II. DRUGS AND DEVICES

1	2	3	4
"Drug" means: (1) Articles recognized in official U. S. Pharmacopeia, official U. S. Homeopathic Pharmacopeia, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of body of man or other animals; and (4) articles intended for use as component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories. (201 (g)) *"Device"* means (except when used in sections of act referring to words, devices, etc., on labeling, and to identification devices). Instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect structure or any function of body of man or other animals. (201 (h)) *"Official compendium"* means: Official U. S. Pharmacopeia, official U. S. Homeopathic Pharmacopeia, official National Formulary, or any supplement to any of them. (201 (j)) *"Antiseptic"*: Representation of drug in its labeling as an antiseptic shall be considered a representation that it is a *germicide*, *except* in the case of a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with body. (201 (o)) *"New drug"* means: (1) Any drug which because of its composition is not generally recognized (among experts qualified by scientific training and experience to evaluate safety of drugs) as safe for use under conditions prescribed, recommended, or suggested in labeling thereof (*except* that: Such a drug not so recognized is not a "new drug" if at any time prior to enactment of this act, it was subject to Food and Drug Act of 1906, as amended, and if at such time its labeling contained *same* representations concerning conditions of its use); or (2) any drug whose composition is such that as a result of investigations to determine its safety for use under conditions prescribed, recommended, or suggested in labeling thereof, it has become recognized (among experts qualified by scientific training and experience to evaluate safety of drugs) as safe for use under such conditions, but has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. (201 (p)) (*Note.*—For definitions of general terms not peculiar to food, drugs, devices, or cosmetics, see above in this column, among definitions for food.)	*Drug or device is adulterated under any of following conditions:* 1. Same as A (1) above, omitting the final "or" clause. (501 (a) (1)) 2. Same as A (2) above. (501 (a) (2)) 3. Same as A (3) above. (*Note.*—Applies to drugs and not to devices.) (501 (a) (3)) 4. It is a drug and it bears or contains, for purposes of coloring only, a *coal-tar color* other than one from a batch certified by Secretary. (501 (a) (4)) 5. It is a drug and any substance has been (*a*) *mixed or packed* therewith so as to *reduce its quality or strength* or (*b*) *substituted* wholly or in part therefor. (501 (d)) 6. It purports to be, or is represented as, a drug whose name is *recognized in an official compendium, and its strength differs* from, or its *quality or purity falls below*, standard set forth in such compendium. *However*, not adulterated under this paragraph if, although it differs from standard of strength, quality, or purity stated in compendium the *difference in strength, quality, or purity is plainly stated on label*. (501 (b)) (Determination as to strength, quality, or purity shall be made in accordance with *tests or methods of assay set forth in such compendium*, except that where such tests or methods are not prescribed therein, or those that are prescribed are, in Secretary's judgment, insufficient for making such determination, he shall bring such fact to attention of appropriate body charged with revision of compendium; and if such body fails within reasonable time to prescribe tests or methods of assay which in Secretary's judgment are sufficient for making determinations of strength, quality, or purity, then he shall make *regulations prescribing* appropriate tests or methods for making such determinations.) (501 (b)) (Whenever drug is recognized in *both U. S. Pharmacopeia*, and *U. S. Homeopathic Pharmacopeia*, shall be subject to requirements of the former, unless it is labeled and offered for sale as a homeopathic drug, in which case shall be subject to provisions of the latter and not to those of the former.) (501 (b)) 7. It does *not* purport to be and is *not* represented as a drug recognized in an official compendium, and its strength *differs from*, or its purity or quality *falls below*, that which it purports or is represented to possess. (501 (c))	*Drug or device is misbranded under any of following conditions:* 1. Same as No. 1 above. (502 (a)) 2. Same as No. 2 above. (502 (b)) 3. Same as No. 3 above. (502 (c)) 4. Same as No. 4 above. (*Note.*—4, 5, and 6 apply to drugs and not to devices.) (502 (i) (1)) 5. Same as No. 5 above. (502 (i) (3)) 6. Same as No. 6 above (*except* that does not have "unless" clause). (502 (i) (2)) 7. Its labeling does not bear (*a*) *adequate directions for use*; and (*b*) such adequate *warnings against use in those pathological conditions* or by children where its use may be dangerous to health, or against *unsafe dosage*, or methods or duration of administration or application in such manner and form as are necessary for protection of users (*Provided*, That where any requirement of clause (*a*) as applied to any drug or device is *not necessary for protection of public health*, Secretary shall make regulations *exempting* such drug or device from such requirement). (502 (f)) 8. It is *dangerous to health when used* in the dosage, or with the frequency or duration prescribed, recommended, or suggested in labeling thereof. (502 (j)) 9. It is for use by man and contains any quantity of the *narcotic or hypnotic substance* alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical *derivative* of foregoing substances, which derivative has been by Secretary, after investigation, found to be, and by regulations designated as, *habit forming*, *unless* label bears name, and quantity or proportion of such substance or derivative and in juxtaposition therewith, statement: "Warning.—May be habit forming." (502 (d) and Act of June 23, 1939, c. 242, sec. 3, 53 Stat. 853) 10. It is a drug and is *not designated solely by a name recognized in an official compendium*, and its label does not bear: (*a*) Common or usual name of drug, if such there be; and (*b*) if fabricated from two or more ingredients, *common or usual name of each active ingredient*, including quantity, kind, and proportion of any alcohol, and also including, whether active or not, *name and quantity or proportion* of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any *derivative or preparation* of any such substances, contained therein (*Provided*, That to extent that compliance with requirements of clause (*b*) is impracticable, exemptions shall be established by Secretary's regulations). (502 (e)) 11. It purports to be a drug whose name is *recognized in an official compendium* and it is *not packaged and labeled as prescribed therein* (*Provided*, the method of packing may be modified with Secretary's consent). (502 (g)) (Whenever drug is recognized in both *U. S. Pharmacopeia* and *U. S. Homeopathic Pharmacopeia*, shall be subject to requirements of the former, with respect to packaging and labeling—*unless* it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to provisions of the latter and not to those of the former.) (502 (g)) 12. It has been found by Secretary to be a drug liable to *deterioration* and is not packaged in such form and manner, and *label* does not bear *statement of such precautions*, as Secretary shall by regulations require as necessary for protection of public health. (But no such regulation shall be established for any drug recognized in an official compendium, until Secretary shall have informed appropriate body charged with revision of such compendium, of need for such packaging or labeling requirements and such body shall have failed within reasonable time to prescribe such requirements.) (502 (h))	Same as above *except* that: (*a*) In No. 4, instead of "emergency permit regulations" read "regulations as to *new drugs*." (*b*) In No. 9, omit phrase "emergency permit regulations or." (301 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k)) (*c*) *Add* following: Using on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505 (as to "New drugs") or that such drug complies with that section. (301 (l))

5	6	7	8	9	10	11
		1. *Coal-tar colors:* Same as above *except* that: After "suitable for use" read "in drugs *for purposes of coloring only*." (504), (706) 2. *Requests for samples:* Same as above. (Note.—Applies to drugs and not to devices.) (702 (b))	3. *Tests or methods of assay:* Secretary shall make regulations prescribing tests or methods of assay for determining strength, quality, or purity of certain drugs under certain conditions. (See No. 6 in column 2). (501(b)) 4. *Drugs liable to deterioration:* Drugs found by Secretary to be liable to deterioration must, to avoid misbranding, be packaged and labeled in accordance with Secretary's regulations. (See No. 12 in column 3.) (502 (h)) 5. *Habit-forming drugs:* Where chemical derivatives of certain drugs have been designated by Secretary's regulations as habit forming, drugs containing such derivatives should bear certain statements on label to avoid misbranding. (See No. 9 in column 3.) (502 (d))	2. *For articles to be processed, repacked, etc.:* Same as No. 2 above *except* that the exemption is to be from "any labeling *or packaging* requirement. . ." (503 (a)) 4. *From specifying ingredients:* Secretary shall make exemptions (to extent that compliance is impracticable) from requirement that where a drug is not designated solely by a name recognized in official compendium, label shall bear names and quantities of certain ingredients (see No. 10 in column 3) to avoid misbranding. (502 (e)) 5. *From stating quantity of contents:* Same as No. 5 above. (502 (b)) (And see also No. 4 proceeding the present item.) 6. *From furnishing parts of samples.* Same as No. 6 above. 7. *From provisions as to new drugs:* Secretary shall make regulations for exempting from operation of section 505 (as to new drugs) drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate safety of drugs. (505 (i)) 8. *From requirement that labeling bear adequate directions for use:* Secretary shall make exemptions from requirement that (where requirement not necessary for protection of public health) labeling of drug or device bear adequate directions for use in order to avoid misbranding. (502 (f))	Same as above. (701 (b)) (801 (b))	Same as above *except* that in 2 (*b*), *list of regulations should read:* 1. Prescribing of methods for testing and assay of drugs. 2. Designation of certain derivatives of substances as habit forming. 3. Prescribing of the packaging and labeling of drugs liable to deterioration. 4. Listing and certifying of coal-tar colors. (701 (a)) (701 (c)) (701 (e)) (701 (g))

12	13	14	15	16	17	18
	1. *General authority and conditions as to applications:* (*a*) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (*b*) below is effective with respect to such drug. (505 (a)) (*b*) Any person may file with Secretary an application with respect to any drug subject to provisions of subsection (*a*) above. Such person shall submit as part of application: (1) Full reports of investigations which have been made to show whether or not such drug is safe for use; (2) full list of articles used as components thereof; (3) full statement of composition thereof; (4) full description of methods used in, and facilities and controls used for, its manufacture, processing, and packing; (5) such samples thereof and of articles used as components thereof, as Secretary may require; and (6) specimens of labeling proposed to be used therefor. (505 (b)) (*c*) An application provided for in subsection (*b*) above shall become effective on sixtieth day after filing thereof, *unless* prior to such day, Secretary by written notice to applicant postpones effective date to such time (not more than 180 days after filing) as Secretary deems necessary to enable him to study and investigate application. (505 (c)) (*d*) If Secretary finds, after due notice to applicant and giving him opportunity for hearing, that (1) the investigations mentioned in subsection (*b*) above do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under conditions prescribed, recommended, or suggested in proposed labeling thereof; (2) results of such tests show that such drug is unsafe for use under such conditions, or do not show that such drug is safe for use under such conditions, (3) methods used in, and facilities and controls used for, manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon basis of information submitted to him as part of application, or on basis of any other information before him with respect to such drug, he has insufficient information to determine whether it is safe for use under such conditions, he shall, prior to effective date of application, issue an order refusing to permit application to become effective. (505 (d)) 2. *Service of orders:* Orders of Secretary issued under this section shall be served (1) in person by any officer or employee of Department designated by Secretary, or (2) by mailing the order, by registered mail addressed to applicant or respondent at his last known address in records of Secretary. (505 (g))	1. *Suspension of granted application:* Effectiveness of application with respect to any drug shall, after due notice and opportunity for hearing to applicant, be suspended by order of Secretary if he finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective, show that such drug is unsafe for use under conditions of use upon basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. Order shall state the findings upon which it is based. (505 (e)) 2. *Revocation of refusal of application:* An order refusing to permit an application to become effective shall be revoked whenever Secretary finds the facts so require. (505 (f)) 3 *Appeal from suspension or refusal of application:* Applicant may appeal from Secretary's order refusing to permit application to become effective or suspending effectiveness of application, by filing in United States district court within any district where applicant resides or has principal place of business, or in United States District Court for District of Columbia, within 60 days after entry of such order, a written petition for setting aside of order. Copy of petition shall be forthwith served upon Secretary, or upon any officer designated by him for that purpose, and thereupon Secretary shall certify and file in court a transcript of record on which the order complained of was entered. Upon such filing, court shall have exclusive jurisdiction to affirm or set aside order. Secretary's *finding as to facts*, if supported by *substantial* evidence, shall be *conclusive*. No objection to Secretary's order shall be considered by court unless it had been urged before Secretary, or unless there were reasonable grounds for failure so to do. If any person shall apply to court for leave to adduce additional evidence and shall show to satisfaction of court that such evidence is material and there were reasonable grounds for failure to adduce it in proceeding before Secretary, court may order it to be taken before Secretary and be adduced upon the hearing in such a way as to court may seem proper. Secretary may modify his findings as to facts by reason of additional evidence so taken, and shall file with court such modified findings (which, if supported by substantial evidence, shall be conclusive) and his recommendation, if any, for setting aside of original order. Judgment and decree of court affirming or setting aside any such order of Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of Judicial Code, as amended, and in section 7, as amended, of "Act to establish a Court of Appeals for the District of Columbia," D. C. Code, title 18, section 26. Commencement of appeal proceedings by applicant shall not, unless specifically ordered by court to contrary, operate as a stay of Secretary's order. (505 (h)) 4. *Exemptions.* Secretary shall make regulations for exempting from this section, drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate safety of drugs. (505 (i))	1. Same as No. 1 above. (502 (b)) 2. Although drug whose name is recognized in official compendium should be packaged and labeled as prescribed therein—the *method of packing may be modified with consent* of Secretary (502 (g))	Same as above *except* that in No 1 (*b*), instead of "emergency permit regulations," read: "provisions as to new drugs." (303 (c) (1)) (303 (c) (2)) (303 (c) (3)) (703)	1. Same as No. 1 above regarding small packages. (502 (b)) 2. Same as 2 (*b*) above regarding *articles to be processed, repacked, etc., except that* the exemption is from labeling "*or packaging*" requirements. (503 (a)) 3. Secretary shall establish exemptions (to extent compliance is impracticable) from requirement that a drug not designated solely by name recognized in official compendium is misbranded unless label bears *names and quantities of certain ingredients*. (See No. 10 (*b*) in column 3.) (502 (e)) 4. Secretary shall make exemptions from requirement (where requirement is not necessary for public health) that labeling of drug or device *bear adequate directions for use* in order to avoid misbranding. (502 (f)) 5. Secretary shall make exemptions from operation of section 505 (as to *new drugs*), for drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate safety of drugs. (505 (i)) 6. A drug dispensed on *written prescription, signed by physician, dentist, or veterinarian* (except drugs dispensed in course of conduct of business of dispensing drugs pursuant to diagnosis by mail), shall if— (1) Such physician, dentist, or veterinarian is licensed by law to administer such drug, and (2) such drug bears label containing name and place of business of dispenser; serial number and date of such prescription; and name of such physician, dentist, or veterinarian, *be exempt from provisions as to misbranding* in sections 502 (b) and 502 (e). (See No. 2 and No. 10 in column 3) And in case such prescription is marked by writer thereof as not refillable, or its refilling is prohibited by law, then the drug is also exempt from misbranding provisions of 502 (d). (See No. 9 in column 3.) (503 (b)) 7. Provision that representation of drug in its labeling as antiseptic, shall be considered a representation that it is a *germicide*, is not applicable to drug purporting to be or represented as an antiseptic for inhibitory use as a *wet dressing, ointment, dusting powder*, or such other use as involves prolonged contact with body. (201 (o))	Same as above *except* that in 1 (*a*) (2), after "misbranded," read: "or in violation of provisions of section 505 as to new drugs" (and note statement that paragraph does not prohibit admission of narcotic drugs the importation of which is permitted under section 2 of act of May 26, 1922, as amended). (801 (a)) (801 (b)) (801 (c)) (801 (d))

19	20	21	22	23	24	25	26	27
Same as above. (302 (a)) (302 (b)) (307)	Same as above. (303 (a)) (303 (b)) (305) (307)	Same as above *except* that in No. 1, instead of "emergency permit regulations," read: "provisions as to new drugs." (304 (a)) (304 (b)) (304 (c)) (304 (e))	Same as above. (304 (a)) (304 (f))	Same as above. (304 (b)) (304 (f))	Same as above *except* that in last sentence, instead of "emergency permit regulations," read "provisions as to new drugs." (304 (d))	Same as above *except:* (*a*) In No. 1, omit second paragraph, (*b*) In No. 2, sampling provision is applicable to drugs but not devices. (702 (a)) (702 (b))	Same as above. (702 (c)) (703) (704)	Same as above. (306)

28	29	30	31
Same as above. (701 (f) (1)) (701 (f) (4)) (701 (f) (5)) (701 (f) (6))	Same as above. (701 (f) (2)) (701 (f) (3))	Same as above *except* that in No. 2, add the following: The use in the advertising relating to any drug of any representation or suggestion that an application with respect to such drug is effective under section 505 (see column 13 as to "new drugs") or that such drug complies with that section, is prohibited. (705 (a)) (705 (b)) (201 (k)) (201 (m)) (301 (l))	1. *To old Food and Drug Law:* Food and Drug Act of 1906, as amended, remains in force until effective date of new act, i. e., until June 25, 1939, with following exceptions: (*a*) There shall be *effective immediately* after June 25, 1938, Secretary's authority to *hold hearings* and *make regulations* under section 701; and following sections (and provisions of act relating to enforcement thereof): section 505, as to *new drugs*, and section 502 (j) regarding *dangerous dosages* suggested in labeling of drugs and devices (see column 3). (902 (a)) (*b*) There shall be effective immediately after May 2, 1939, section 706 as to listing and certification of coal-tar colors (see No. 1 in column 7). (Act of May 2, 1939, c. 107, title 1, 53 Stat. 631.) (*c*) Effective date of labeling provisions in sections 501 (a) (4); 502 (b), (d), (e), (f), (g), (h) (see column 3) is *postponed until January 1, 1940*. (Act of June 23, 1939, c. 242, sec. 1 (a), 53 Stat. 853.) (*d*) Secretary shall make regulations further *postponing to July 1, 1940*, effective date of provisions in (c) above (excluding section 501 (a) (4)) with respect to lithographed labeling manufactured prior to February 1, 1939, and to containers bearing labeling which prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused, or blown on or in such containers, where compliance with said provisions would be unduly burdensome by causing loss of valuable stocks of such labeling or containers and where such postponement would not prevent public interest from being adequately served. However, postponement shall not apply to labeling which would not have complied with Food and Drug Act of 1906, as amended. (Act of June 23, 1939, c. 242, sec. 1 (b), 53 Stat. 853.) (*e*) Notwithstanding listing of section 502 (d) and (e) of 1938 act among postponed provisions, they are *not postponed insofar* as they relate to *any of the following substances or derivatives thereof:* Alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, acetanilid; nor is section 502 (b), (d), (e), (f), (g), (h) postponed insofar as it relates to "*new drugs*." (Act of June 23, 1939, c. 242, sec. 2 (c), 53 Stat. 853.) 2. *To other laws:* Section 801 (a) relating to imports shall not be construed to prohibit admission of narcotic drugs the importation of which is permitted under section 2 of act of May 26, 1922, as amended. (801 (a))

III. COSMETICS

1	2	3	4
"Cosmetic" means: (1) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; *except* that such term shall not include soap. (201 (i)) (*Note.*—For definitions of general terms not peculiar to food, drugs, devices, or cosmetics, see above in this column, among definitions for food.)	*Cosmetic is adulterated under any of following conditions:* 1. Same as A (1) above for food, omitting the final "or" clause. (601 (b)) 2. Same as A (2) above for food. (601 (c)) 3. Same as A (3) above for food. (601 (d)) 4. It bears or contains any *poisonous or deleterious substance* which may render it injurious to users under conditions of use prescribed in labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to *coal-tar hair dye*, label of which bears following legend conspicuously displayed thereon: "Caution.—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and labeling of which bears *adequate direction for such preliminary testing*. (For purposes of this paragraph, term "hair dye" shall not include eyelash dyes or eyebrow dyes.) (601 (a)) 5. It is *not a hair dye* and it bears or contains a *coal-tar color* other than one from a batch certified in accordance with Secretary's regulations. (See column 7.) (601 (e)) (For purposes of this paragraph, term "hair dye" shall not include eyelash dyes or eyebrow dyes.) (601 (a))	Same as Nos. 1, 2, 3, 4, above, for food. (602 (a)) (602 (b)) (602 (c)) (602 (d))	Same as provisions above for food *except* that: (*a*) No. 4 is omitted. (*b*) In No. 9 omit reference to "emergency permit regulations or." (301 (a)) (301 (b)) (301 (c)) (301 (e)) (301 (f)) (301 (g)) (301 (h)) (301 (i)) (301 (j)) (301 (k))

5	6	7	8	9	10	11
		1. *Coal-tar colors:* Same as above for food. (604) 2. *Requests for samples:* Same as above for food. (702 (b))		2. *For articles to be processed, repacked, etc.:* Same as above for food. (603) 5. *From stating quantity of contents:* Same as above for food. (602 (b) (2))	Same as above. (701 (b)) (801 (b))	Same as above for food *except* that in 2 (*b*), list of regulations should include *only:* Listing and certifying of coal-tar colors. (701 (e))

12	13	14	15	16	17	18
			Same as No. 1 above for food. (602 (b))	Same as above for food *except:* In 1 (*b*) omit reference to emergency permit regulations. (303 (c) (1)) (303 (c) (2)) (303 (c) (3)) (703)	1. Same as No. 1 above for food, regarding *small packages*. (602 (b)) 2. Same as No. 2 (*b*) above for food, regarding articles to be *processed, repacked*, etc. (603) 3. *Soap* is specifically excluded from regulation of cosmetics. (201 (i))	Same as above for food. (801 (a)) (801 (b)) (801 (c)) (801 (d))

19	20	21	22	23	24	25	26	27
Same as above. (302 (a)) (302 (b)) (307)	Same as above. (303 (a)) (303 (b)) (305) (307)	Same as above for food, omitting reference in No. 1, to emergency permit regulations. (304 (a)) (304 (b)) (304 (c)) (304 (e))	Same as above. (304 (a)) (304 (f))	Same as above. (304 (b)) (304 (f))	Same as above for food, omitting last sentence. (304 (d))	Same as above for food, *except* that in No. 1, omit second paragraph. (702 (a)) (702 (b))	Same as above. (702 (c)) (703) (704)	Same as above. (306)

28	29	30	31
Same as above. (701 (f) (1)) (701 (f) (4)) (701 (f) (5)) (701 (f) (6))	Same as above. (701 (f) (2)) (701 (f) (3))	Same as above for food. (703 (a)) (705 (b)) (201 (k)) (201 (m))	1. *To old Food and Drug Law:* Food and Drug Act of 1906, as amended, remains in force until effective date of new act, i. e., until June 25, 1939, with following exceptions: (*a*) There shall be *effective immediately* after June 25, 1938: Secretary's authority to *hold hearings* and *make regulations* under section 701; and section 601 (a) regarding adulterated cosmetics (with clause therein as to coal-tar hair dyes being effective 90 days later). (See No. 4 in column 2) (902 (a)) (*b*) There shall be effective immediately after May 2, 1939, section 706 as to listing and certification of coal-tar colors (see No. 1 in column 7.) (Act of May 2, 1939, c. 107, title I, 53 Stat. 631.) (*c*) Effective date of labeling provisions in sections 601 (e) and 602 (b) (see column 3) is *postponed until January 1, 1940*. (Act of June 23, 1939, c. 242, sec. 1 (a), 53 Stat. 853.) (*d*) Secretary shall make regulations further *postponing to July 1, 1940*, effective date of labeling provisions of section 602 (b) (see column 3) with respect to lithographed labeling manufactured prior to February 1, 1939, and to containers bearing labeling which prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused, or blown on or in such containers where compliance with said provisions would be unduly burdensome by causing loss of valuable stocks of such labeling or containers and where such postponement would not prevent public interest from being adequately served. However, postponement shall not apply to labeling which would not have complied with Food and Drug Act of 1906, as amended. (Act of June 23, 1939, c. 242, sec. 1 (b), 53 Stat. 853.)

*NOTE.—(1) The exact language of the statute has been reproduced, except for minor variations aimed at economy of expression (e. g., omissions of "the," "an," etc) (2) In some columns, the same material is given as in other columns. This results from the intention to analyze the law from several approaches, some of which overlap. Thus, most of the material in columns 7, 8, 9, 10, will also be found in other columns, but it was deemed useful to group together all the provisions relating to administrative as distinguished from legislative regulations. (3) Except where otherwise indicated, a reference in the "Drugs and Devices" columns, or the "Cosmetics" columns, that a provision is the "same" as the one above for "Food," means that it is exactly the same. (4) Any provision in the "Drugs and Devices" columns applies to both drugs and devices, except where otherwise indicated. (5) A useful feature of the chart is the concentration, by cross-references or by juxtaposition, of provisions which may be far apart in the act, but are relevant to the same point. Another useful feature is the ease of comparing on each point, the kinds of regulations applicable respectively to food, drugs, devices, and cosmetics. (6) The column titles make it a simple, quick matter to find a desired item And the inclusion of section numbers for each point makes it possible to obtain the official citation without searching through the act itself. (7) The citation given at the end of each provision refers to the appropriate section number of the 1938 act; when the citation is to the 1939 amendatory act, that fact is indicated. (8) Italics occurring throughout the chart are not in the law, but are supplied as a convenience to the reader.

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